

**TRANSMITTED BY FACSIMILE**

Jan Tomsic  
Director, Regulatory Affairs  
Connetics Corporation  
3400 West Bayshore Road  
Palo Alto, CA 94303

**RE: Luxiq™ (betamethasone valerate) Foam, 0.12%**  
NDA 20-934  
MACMIS ID#10224

Dear Ms. Tomsic:

This letter objects to Connetics Corporation's (Connetics) dissemination of violative promotional materials for Luxiq (betamethasone valerate) Foam. As part of its monitoring program, the Division of Drug Marketing, Advertising and Communications (DDMAC) has become aware of direct-to-consumer (DTC) radio advertisements, professional promotional labeling, and website for Luxiq that are false or misleading, in violation of the Federal Food, Drug, and Cosmetic Act (Act) and its implementing regulations. The DTC broadcast radio advertisements ("Luxiq DTC Radio Campaign (CNX16825) Common problems-spot 1,2, and 3"), professional promotional labeling ("Luxiq 2001 Radio Campaign") and website ([www.luxiq.com](http://www.luxiq.com)) submitted under FDA Form 2253 are violative for the reasons described below.

**Overstatement of Efficacy**

Luxiq's approved product labeling (PI) includes results from a clinical trial in 159 patients with moderate to severe scalp psoriasis demonstrating that Luxiq decreased scaling, erythema, and plaque thickness by 47%, 41% and 66%, respectively. In your advertisements, you present the claims "90-100% clearance in the majority of patients (72%) in 28 days, in a phase III clinical trial" and "Tests show that Luxiq provides rapid and highly effective relief in three out of four patients." These claims are misleading because they are inconsistent with your PI and are an overstatement of the efficacy of Luxiq.

In addition, the trial described in the PI included patients who were treated twice daily for four weeks. According to the PI, "At four weeks of treatment, study results of 159 patients demonstrated that the efficacy of Luxiq Foam in treating scalp psoriasis is superior to that of Placebo foam, and is comparable to that of a currently marketed BMV lotion." Your website includes the statements:

"How long will it take to see and feel results? Luxiq has been proven to deliver rapid and effective results. In clinical trials, Luxiq reduced the signs and symptoms of skin irritation (scaling, redness, and plaques) within days of treatment."

These statements are misleading because they are inconsistent with the PI and overstate the efficacy of Luxiq with respect to how long it takes to see results.

### **Preference and Compliance Claims**

Your advertisements include claims such as “In research with patients, more than 80% preferred foam over lotions, solution, gels, creams, ointments and oils,” and “80% of patients surveyed preferred Luxiq foam over lotions, gels and other treatments.” These claims are misleading because the references provided are insufficient to support these preference claims. Specifically, outcomes claims, including product preference claims, require substantial evidence as measured by adequate and well-controlled trials using well-developed and validated measures. Focus group research is not adequate and well-controlled.

Similarly, your claim “Patients prefer its quick-drying, stain-free and non-dripping qualities, which may enhance a patient’s comfort and compliance” is misleading because the references provided are insufficient to support these claims. These outcomes claims, i.e., enhanced comfort and enhanced compliance, require substantial evidence as measured by adequate and well-controlled trials using well-developed and validated measures. The reference provided described only a theoretical discussion of these outcomes, not a study that actually measured them.

### **Superiority Claims**

Your website contains the statements “Other scalp treatments such as ointments and solutions are oily, drippy, or messy, and may be inconvenient. For all these reasons, you may find Luxiq better for you.” Similarly, your radio advertisement states “Every prescription scalp treatment I use has some kind of drawback. The only way I’d try something new is if it were proven really safe and effective.” These presentations are misleading because they imply that Luxiq is superior to other products on the market when such has not been demonstrated by substantial evidence. Your PI states that “At four weeks of treatment, study results of 159 patients demonstrated that the efficacy of Luxiq Foam in treating scalp psoriasis is superior to that of Placebo foam, and is *comparable* to that of a currently marketed BMV lotion (emphasis added).”

### **Requested Action**

Connetics should immediately discontinue these and all other promotional materials and activities for Luxiq that contain the same or similar claims or presentations. We request that Connetics respond, in writing, with its intent to comply with the above. DDMAC should receive your written response no later than August 22, 2001. This response should list similarly violative materials with a description of the method for discontinuation and the discontinuation date.

If you have any questions or comments, please contact me by facsimile at (301) 594-6771, or at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, HFD-42, Rm. 17B-20, 5600 Fishers Lane, Rockville, MD 20857. DDMAC reminds you that only written communications are considered official.

Jan Tomsic  
Cometics Corporation  
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In all future correspondence regarding this particular matter, please refer to MACMIS ID #10224 in addition to the NDA number.

Sincerely,

*{See appended electronic signature page}*

Barbara S. Chong, Pharm.D., BCPS  
Regulatory Review Officer  
Division of Drug Marketing,  
Advertising and Communications

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**This is a representation of an electronic record that was signed electronically and  
this page is the manifestation of the electronic signature.**

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/s/

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Barbara Chong  
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**"Common Problem" Proven Safe, 60 sec.**

**V/O:** Frustrated by an itchy, flaky scalp condition such as dandruff, psoriasis or eczema, you're not alone...

**Woman:** Every prescription scalp treatment I use has some kind of drawback. The only way I'd try something new is if it were proven really safe and really effective.

**V/O:** It's time to ask your dermatologist about Luxiq - it contains betamethasone valerate, a medication that's been prescribed safely for over 34 years. The difference is, Luxiq is the first medication to come in a light foam. It absorbs quickly and works. Tests show that Luxiq provides rapid and highly effective relief in three out of four patients!

Luxiq is a prescription medication used to relieve skin problems on the scalp such as psoriasis that can be treated with topical steroids. The most frequent side effects are mild temporary burning, stinging, or itching at the application site.

Want relief without grief? Ask your dermatologist about Luxiq. Call for FREE information and a coupon to redeem with your Luxiq prescription: Call 1-800-123-4567. That's 1-800-123-4567. Or visit: L-U-X-I-Q.com

**"Common Problem" Elegant Solution Spot, 60 sec.**

V/O Frustrated by an itchy, flaky scalp condition such as dandruff, psoriasis or eczema, you're not alone...

**Woman:** I haven't worn a black dress in years.

**Man:** When it flares up, I get really self-conscious - and my lotion is so greasy.

**V/O:** It's time to ask your dermatologist about Luxiq - the first prescription scalp medication that's a soft foam. You just apply a fingertip of Luxiq to the affected area and it dries in seconds with no dripping, greasiness or residue. 80% of patients surveyed preferred Luxiq foam over lotions, gels and other treatments. And it works fast too.

Luxiq is prescription medication used to relieve skin problems on the scalp such as psoriasis that can be treated with topical steroids. The most frequent side effects are mild temporary burning, stinging, or itching at the application site.

Want relief without grief? Ask your dermatologist about Luxiq. Call for FREE information and a coupon to redeem with your Luxiq prescription: Call 1-800-123-4567. That's 1-800-123-4567. Or visit: L-U-X-I-Q.com.

**"Common Problem" Proven Effective, 60 sec.**

V/O Frustrated by an itchy, flaky scalp condition such as dandruff, psoriasis or eczema, listen to what Dr. Del Rosso, Board Certified Dermatologist has to say Luxiq Foam.

**Dr. Del Rosso:** Every day I see patients who are embarrassed and irritated by their scalp conditions. That's why I'm encouraged by the results in patients I've treated with Luxiq foam. Tests show that three out of four patients get rapid and highly effective relief with Luxiq - and my own results confirm this. Patients can apply Luxiq just before they run out the door in the morning because it's not messy or greasy and leaves no visible residue. There's nothing else like it.

Luxiq is a prescription medication used to relieve skin problems on the scalp such as psoriasis that can be treated with topical steroids. The most frequent side effects are mild temporary burning, stinging, or itching at the application site.

**V/O:** Want relief without grief? Ask your dermatologist about Luxiq. Call for FREE information and a coupon to redeem with your Luxiq prescription: Call 1-800-123-4567. That's 1-800-123-4567. Or visit L-U-X-I-Q.com

## Reaching out to your typical patients with an atypical topical.

This direct-to-consumer radio campaign program raises awareness of an elegant and effective treatment for scalp

dermatoses. It emphasizes Luxiq's ability to provide fast, effective relief delivered in a unique foam modality that patients prefer.<sup>1</sup>

As you can see, Luxiq delivers results that are anything but typical...

- 90 – 100% clearance in the majority of patients (72%) in 28 days, in a phase III clinical trial<sup>2</sup>
- In research with patients, more than 80% preferred foam over lotions, solutions, gels, creams, ointments and oils<sup>3</sup>
- Patients prefer its quick-drying, stain-free and non-dripping qualities,<sup>3</sup> which may enhance a patient's comfort and compliance
- A well-established safety profile<sup>2</sup>

**Luxiq** 

(betamethasone valerate) Foam, 0.12%

An elegant means to an effective end.

Luxiq is a medium potency topical corticosteroid indicated for relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses of the scalp such as psoriasis, eczema and seborrheic dermatitis. The most frequent side effects associated with the use of Luxiq are mild and transient burning, stinging or itching at the application site.

 **connetics**  
Delivering Innovation to Dermatology

[www.luxiq.com](http://www.luxiq.com)

© 2001 Connetics Corporation. The foam icon is a trademark, and Luxiq, Connetics, and the circle-globe design are registered trademarks of Connetics Corporation.

References: 1. Data on file [002], Connetics Corporation. 2. Franz TJ, Parsell DA, Halusani RM, et al. Betamethasone valerate foam 0.12%: a novel vehicle with enhanced delivery and efficacy. *INT J Dermatol*. 1999;38:628-632. 3. Data on file [003], Connetics Corporation. 4. Feldman SR, Sangha N, Setakuri V. Topical corticosteroid in foam vehicle offers comparable coverage compared with traditional vehicles. *J Am Acad Dermatol*. 2000;42(6):1017-1020.



## About Luxiq Foam

### ► Frequently Asked Questions

How often should I apply Luxiq Foam?

How long will it take to see and feel results?

Can I bandage the affected area after applying Luxiq Foam?

Can I stop using Luxiq Foam as soon as I see my scalp condition clearing up?

What should I do if I miss a dose?

Are there any side effects associated with Luxiq Foam?

What size cans of Luxiq Foam are available?

How do I take advantage of the Luxiq Foam savings certificates?

**Q How often should I apply Luxiq Foam?**

Typically, you should apply Luxiq twice a day (once in the morning and again at night). It is important to follow your doctor's directions. ▲

**Q How long will it take to see and feel results?**

Luxiq has been proven to deliver rapid and effective results. In clinical trials, Luxiq reduced the signs and symptoms of skin irritation (scaling, redness, and plaques) within days of treatment.

**Q Can I bandage the affected area after applying Luxiq Foam?**

Unless directed by your doctor, do not bandage or cover the treated area. The treated areas should be left open to air. ▲

**Q Can I stop using Luxiq Foam as soon as I**

## About Luxiq Foam

### ►What is Luxiq Foam?

Luxiq is the brand name for a unique foam formulation of betamethasone valerate, a prescription medication known as a topical corticosteroid. Luxiq provides rapid and highly effective relief from the swelling, redness, itching, and tenderness caused by certain skin conditions.

### ►Why does Luxiq come in a foam?

The soft, white foam quickly carries the medication right to the affected area. And it's much easier, and much more pleasant to deal with. Fast, accurate delivery of medication. Quick-drying—leaves no greasy residue. Nondripping. So it stays where you put it. Won't stain clothing or bed linens. Fragrance-free. (The faint alcohol scent you may notice disappears as the foam dries.) Can be used anywhere: at home, at work, even in the locker room.

### ►How is Luxiq Foam different from other scalp medications?

Luxiq delivers its medication right to the affected area—even in hard-to-treat areas like the scalp. Here's how. First of all, the unique foam stays where you put it.

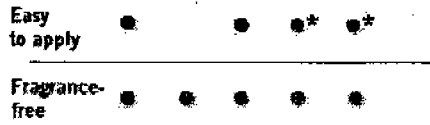
Then your body heat causes the foam to melt—so all of the medication is where you need it to work. Other scalp treatments such as ointments and solutions are oily, drippy, or messy, and may be inconvenient. For all these reasons, you may find Luxiq better for you.

Luxiq Foam is elegantly delivered<sup>2</sup>

	Luxiq (Foam)	Lotion/Solution	Gel	Cream	Ointment	Oil
No residue	●	●				
Stain-free	●	●	●			
Dries quickly	●					
Non-dripping	●		●	●	●	●

better for you.

In fact, in research with patients, more than 80% said they preferred using foam over lotions, solutions, gels, creams, ointments, and oils.<sup>1</sup>



\*Not easy to apply to hairy areas

References: 1. Data on file [002], Connetics Corporation. 2. Data on file [003], Connetics Corporation.

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The atypical topical™



The fact is, Luxiq achieves 90–100% clearance of scalp psoriasis in a majority of patients (72%) in 28 days versus 47% of patients treated with betamethasone valerate lotion, while preserving the safety profile of BMV.<sup>1</sup>



Patients prefer it too.<sup>2</sup> Luxiq is rapidly disappearing, quick-drying, and fragrance-free. It leaves no greasy residue to damage clothing or bed linens.

Deliver enhanced efficacy with mid-potency safety. Prescribe the atypical topical—Luxiq Foam.

References: 1. Franz TJ, Parsell DA, Halualani RM, *et al.* Betamethasone valerate foam 0.12%: a novel vehicle with enhanced delivery and efficacy. *Int J Dermatol.* 1999;38:628-632. 2. Data on file [003], Connetics Corporation.

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